

**REMARKS**

Favorable reconsideration is respectfully requested in view of the foregoing amendments and the following remarks.

**I. CLAIM STATUS AND AMENDMENTS**

Claims 9 and 11-24 were pending in this application when last examined.

Claims 11-24 were withdrawn as non-elected subject matter.

Claim 9 stands rejected.

Applicants reserve the right to file a Continuation or Divisional Application on any cancelled or withdrawn subject matter.

Claim 9 is amended to disclose a method for purifying a human sweat fraction. Support for such claim can be found in the specification as filed, see for example, page 10, line 11 to page 11, line 13.

No new matter has been added.

**II. UTILITY/ENABLEMENT REJECTIONS**

On pages 2-4, claim 9 was rejected under 35 U.S.C. § 101 as lacking utility.

On pages 5-7, claim 9 was rejected under 35 U.S.C. § 112, first paragraph, as not enabling since no utility was found.

Applicants respectfully traverse this rejection as applied to amended claim 9.

The Examiner's position is that the asserted utility is not specific and substantial because the specification does not identify the sweat fraction, its biological role, or its significance.

Further, the Examiner contends that the invention requires further research and characterization to determine the compound which binds the composition of claim 1.

The Examiner does concede that the Applicants enable a process for purifying a human sweat fraction.

Applicants note that claim 9 has been amended to teach a method of purifying a human sweat fraction having functional characteristics as described therein. The structure of the compound is not a limitation of the claimed method. The Applicants note that the method has credible utility because 90% of patients with atopic dermatitis were correctly diagnosed using the sweat fraction produced by the method of amended claim 9. See Examples 1, 2 and 5. Further,

the Examiner has conceded that the specification as filed enables a method for purifying human sweat. Accordingly, these rejections are untenable and must be withdrawn.

### **III. IMPROPER CLAIM REJECTION**

On pages 4 and 5, claim 9 was rejected under 35 U.S.C. § 112, second paragraph as being incomplete for omitting essential elements of the composition.

Claim 9 has been amended to recite all the steps necessary to obtain the claimed human sweat fraction. Thus, this rejection is untenable and should be withdrawn.

### **IV. ENABLEMENT REJECTION**

On pages 7-9, claim 9 was rejected under 35 U.S.C. § 112, first paragraph for not reasonably providing enablement for a composition.

As noted above, claim 9 is amended to recite a method of obtaining a composition. Applicants note that there is no requirement that said method sets forth all the components of said composition. Thus, this rejection is untenable and should be withdrawn.

### **V. WRITTEN DESCRIPTION REJECTION**

On pages 9 and 10, claim 9 was rejected under 35 U.S.C. § 112, first paragraph, for not having been in possession of the composition at the time the application was filed.

It is noted that Examples 1, 2 and 5 are directed towards the method of the amended claim 9. Thus, possession of the claimed invention is demonstrated and this rejection is untenable and should be withdrawn.

### **VI. ANTICIPATION REJECTION**

On page 11 and 12, claim 9 was rejected under 35 U.S.C. § 102 as being anticipated by Hide et al. (hereinafter Hide).

Applicants respectfully traverse this rejection as applied to amended claim 9.

Specifically, the Examiner asserts that Hide teaches the composition of claim 9.

The Examiner concedes that Hide does not teach or suggest the process steps claim 9. However, the Examiner argues that since claim 9 is a product-by-process claim, the patentability of the invention depends on the product and not the method of production.

As noted above, amended claim 9 is directed to a method. Since the Examiner contends that Hide only teaches a composition and does not disclose the method limitations of amended claim 9, Hide cannot anticipate the claimed invention.

Therefore, this rejection is untenable and should be withdrawn.

### CONCLUSION

In view of the foregoing amendments and remarks, it is respectfully submitted that the present application is in condition for allowance and early notice to that effect is hereby requested.

If the Examiner has any comments or proposals for expediting prosecution, please contact the undersigned attorney at the telephone number below.

Respectfully submitted,

Michihiro HIDE et al.

/William R.  
Schmidt, II/  
By:

Digitally signed by /William R. Schmidt, II/  
DN: cn=/William R. Schmidt, II, o=WLP,  
ou=email-facsimile@wendeleroth.com,  
c=US  
Date: 2009.07.09 12:59:23 -04'00'

William R. Schmidt, II  
Registration No. 58,327  
Attorney for Applicants

WRS/cg/vah  
Washington, D.C. 20005-1503  
Telephone (202) 721-8200  
Facsimile (202) 721-8250  
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